



31<sup>st</sup> May 2019

Version: 1.3

# **PharmaTrac**

**Software Requirements and Specifications- SRS** 

Supply Chain Solutions
Signode India Limited
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# **Contents**

Modifi	cation History	2
Abbre	viations / Terminology	2
1.0	Objective of PharmaTrac	3
2.0	Requirement / Features	3
3.0	Proposed - Process	3
4.0	PharmaTrac – Software Requirements:	4
4.1.	System set up	4
4.2.	Integration with ERP:	4
4.3.	Scan, validate and recording of box of 300:	6
4.4.	Tertiary / Shipper carton Labelling	9
4.5.	Automatic weighment:	.2
4.6.	Back track facility:	.3
4.7.	Reports:	.4
4.8.	Scope of Serum	.4
5.0.	Sign-Off:	.5
Appen	dix A: Review Comments and Responses:1	.6
<u>List o</u>	f Figures:	
Figure	1. PharmaTrac - Overview	3
Figure	2. 300 box label	6
Figure	3. PharmaTrac - Login UI	8
Figure	4. DO and Scanning of Secondary boxes	9
Figure	5. Generation of shipper carton and validation	.2



# **Modification History**

Revision	Date	Originator	Comments
1	28 <sup>th</sup> May 2019	Sunil K. Raj Sodadasi	Initial Version
2	30 <sup>th</sup> May 2019	Ajit Gulanikar, ITD, Serum	Feedback on the SRS and indicated in the appendix

# **Abbreviations / Terminology**



### 1.0 Objective of PharmaTrac

Serum Institute of India endeavors to implement Track N trace solution tightly integrated with the Signode Packaging line to achieve the below:

- ✓ Automatic label application for the master cartons
- ✓ Maintain traceability of the Box of 300 and the Shipper Cartons

## 2.0 Requirement / Features

- ✓ Get the dispatch orders from ERP in the form of .csv file
- ✓ UI to input / select the DO from the kiosk and automatic populate the Do details with status
- ✓ Fixed scanner to read and validate the 300 Box label
- ✓ Unique ID generation for each shipper as per the SSCC
- ✓ Automatic Print & Apply system for the master cartons
- ✓ Integration with weighment scales for automatic weighment
- ✓ Audible and visual alerts and exceptions
- ✓ Ability for backward integration of Traceability of Box of 300
- ✓ Customized reports –DO report and exception report; day wise / shift wise reports

### 3.0 Proposed - Process

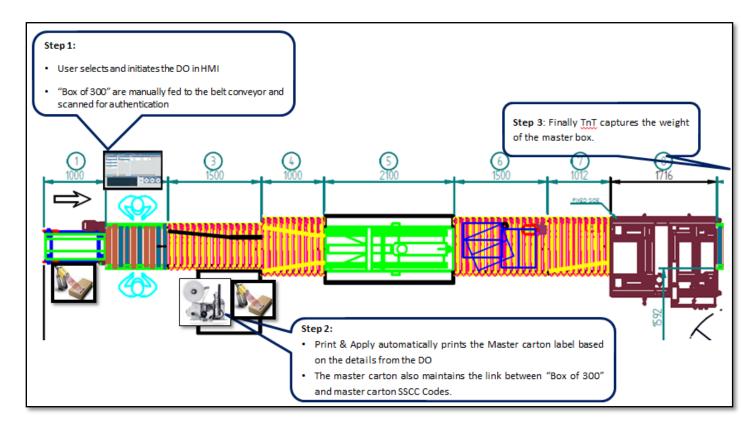


Figure 1. PharmaTrac - Overview



## 4.0 PharmaTrac - Software Requirements:

#### 4.1. System set up

- Industrial grade kiosk to act as a server for PharmaTrac and to host the software
- SAP GUI to install on the server and down load the DOs for every certain period of time
- Fixed barcode scanners to read the box of 300 and Shipper carton
- Automatic print and apply the customized barcode on the shipper carton
- Sensors on the conveyor to detect the object movement for scanning and label application
- Barcode printer to print the temporary barcode label once the strapping and wrapping is completed
- Wired scanner to scan the temporary barcode and capture the weighment automatically

#### 4.2. Integration with ERP:

- Signode will create a shared folder in the PharmaTrac server to receive incoming DO files from SAP
- Separate folders for Inward and Outward process
  - o Inward: To keep the DO which are from ERP i.e. SAP-to- Signode.xlsx
  - Outward: To store the DO confirmation file to ERP i.e. Signode-to-SAP.xlsx
  - o Exception: To keep the DO with exception
- Sample 3 files which would be exchanged as shown in the below
  - Header
  - Batch
  - Secondary

#### **Header file:**

DO Number	187030407
Product Name	MV 10 DOSE (ENGLISH WHO) VVM
GTIN-Inner	28901213041902
GTIN-Outer	58901213041903
Shipper Dimension	60 X 48 X 41
Qty per Shipper	1200
No of Secondary per shipper	4
Gross wt	25
Net wt	10.9
Cons-Line 1	PO NO. 45164810
Cons-Line 2	REF: GAVI-NGA-19 MEASLES VACCINE-NIGERIA
Cons-Line 3	CUSTOMER REF: PSS – GAVI-NGA-19 MEA VAC
Cons-Line 4	NATIONAL PRIMARY HEALTH CARE
Cons-Line 5	DEVELOPMENT AGENCY (NPHCDA)
Cons-Line 6	PLOT 681/682 PORT HARCOURT CRESCENT



Cons-Line 7	OFF GIMBIYA STREET, GARKI AREA II
Cons-Line 8	ABUJA, NIGERIA, NIGERIA VIA ABUJA
Cons-Line 9	TEL: (234)9 670 1741;(234) 803 452 0197

Note: In the Excel file it would be in single row but for display purpse, we have showed in multiple rows)

#### **Batch file:**

DO	Batch	MFG	EXP
Number	Number		
187030407	0048F111	DEC 2018	MAY 2021
187030407	0048F112	JAN 2019	JUN 2021
187030407	0048F113	JAN 2019	JUN 2021

#### Secondary file:

DO	Shipper No	Box No.	Batch	
Number				QTY
187030407	1	1	0048F111	300
187030407	1	2	0048F111	300
187030407	1	3	0048F111	300
187030407	1	4	0048F111	300
187030407	2	1	0048F111	300
187030407	2	2	0048F111	300
187030407	2	3	0048F111	300
187030407	2	4	0048F111	300
187030407	3	1	0048F111	300

- Display the list of DOs which are imported automatically in the PharmaTrac
- Maintain the status of the DO
  - o Pending: which is imported and process is not started
  - o In-progress: Process is started and in process
  - o Done: DO is completed
- Facility to take the backup of the imported file
- Facility to share the DO files with ERP against completion of DO
- PharmaTrac places the file in the shared folder and SAP has to fetch the DO which contains the additional fields like captured weight, Time stamp, user details etc.
- DO files would be deleted from the folder for every certain period of time



## 4.3. Scan, validate and recording of box of 300:

- Pre-requisites:
  - Inputs files on the dispatch order would available in the shared folder 3 set of files –
     Header, Batch and Secondary
  - o The above file are tab delimited format
  - Only current dispatch order files would be placed in the folder and completed files would be deleted
- Scanning process:
  - Operator logs onto PharmaTrac
  - Facility to select / manually input the DO which is pending or Inprogress
    - Completed DOs will not be displayed in the drop down
- Display the list of selected DO details includes DO, Batch Numbers, Expiry Date Qty, Sequence of batches and sequence of boxes
- Operator manually places the box of 300 on the conveyor
- Based on the sensor trigger on the conveyor, fixed barcode scanner scans the barcode on the box of 300
  - o Alternate process to input the Serial Number of the secondary carton
- PharmaTrac decodes the data against the 300 carton box and as indicated in the below
  - o Batch No of the 300 box
  - o GTIN Number
  - Expiry date and
  - o Unique ID



Figure 2. 300 box label

- Application validates the barcode on the box of 300 for the below:
  - GTIN as per the GTIN-inner in the Header file
  - o Batch No
  - Expiry date



- Sequence of the batch and sequence of the box
- Below are the notifications
  - o Triggers 'Green color' if the barcode is valid against the DO and sequence
  - o Trigger 'RED' color if the scanned barcode is invalid against the DO and sequence
  - o Triggers the audible alert incase of invalid barcode scanning
  - o Alternate option to stop the conveyor if the scanned barcode is invalid
- If the barcode is valid and displays on the kiosk and automatically records the scanned box in the below format

DO Number	Shipper No	Вох	Batch	QTY	GTIN No	Expiry	Label	User	Time stamp
		No.							
187030407	1	1	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:10
187030407	1	2	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:11
187030407	1	3	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:12
187030407	1	4	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:13
187030407	2	1	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:14
187030407	2	2	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:15
187030407	2	3	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:15
187030407	2	4	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:16
187030407	3	1	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:17
187030407	3	2	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:18
187030407	3	3	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:19
187030407	3	4	0048F111	300	28901213041902	DEC	S	Ajit	28052019
						2018			10:10:20

- Below are the list of other scenarios:
  - o There will be some boxes having less Qty than the standard
  - o There can be multiple batches in a shipper
  - There can be less than 4 boxes in a shipper and also happen for a shipper in the middle (when temperature recorder is inserted in that shipper)
- Automatically records the secondary 300 box and generates the unique shipper ID as per the Secondary file



- Displays on the screen for the list of shipper ID with print status
- Status of the DO would be updated and displayed against each scan of 300 Box



Figure 3. PharmaTrac - Login UI



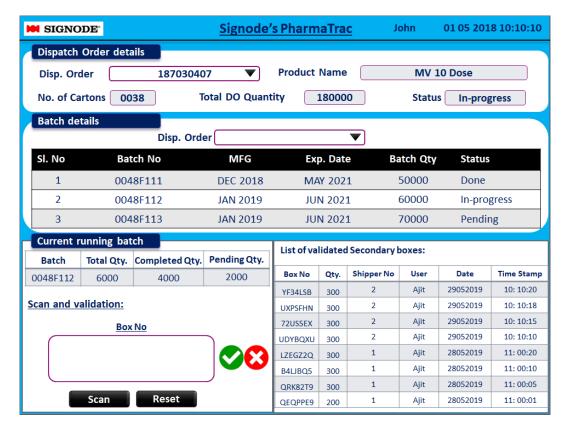


Figure 4. DO and Scanning of Secondary boxes

#### 4.4. Tertiary / Shipper carton Labelling

- Operator manually collects the cartons and place it in the shipper carton
  - User has to pack the boxes in the same sequence as received from the belt conveyor to maintain the right traceability till the end
- Once the required quantity is placed in the shipper carton and pack the shipper carton
- User places the shipper carton on the conveyor for automatic printing and labelling
- Shipper label generation:
  - o PharmaTrac generates an unique ID for shipper carton based on SSCC.
  - o Sample tertiary Ex: 02 8901213 123456789 3
  - Content of SSCC
    - First digit: 3 This is digit is for the 'extension' which is allotted to Signode PharmaTrac
    - Next 9 digits are for Serum GS1 unique number i.e. 8901213
    - Next 9 digits are for running unique serial number per shipper
    - Next: 1 is for check digit
- Other scenarios:
  - The secondary carton contains multiple batches:
    - In this case, the batch number and expiry date would be blank on the label



- Need to print only SSCC number of the tertiary carton and also the barcode. No need to print the barcode with GTIN, Batch and expiry
- Calculates the theoretical weight as per the loaded secondary boxes onto the shipper carton
- Based on the sensor trigger, PharmaTrac prints and apply the label automatically
- The content of the shipper label:
  - Delivery NO would be printed as per the Header file
  - Description of the DO / Product Name would be printed as per the header file
  - Theoretical Net weight and Gross weight in KG would be calculated as per the quantity of the boxes (As per the secondary file) and also other packaging accessories
  - Gross Weight / Net weight to be printed on shipper: This would be made on pro-rata basis if the shipper contains less that the standard quantity specified in HEAD
  - o Dimension of the shipper as per the Header file
  - Quantity would be printed based on the 'Quantity per shipper' which is mentioned in the secondary file of one particular DO. This is based on the actual scanning of the secondary boxes and quantity of each box as derived from SECONDARY file
  - o Batch Number and Expiry Date as per the DO and Batch file
  - If Shipper contains multiple secondary boxes, then the Batch No and Expiry Date would be blank
  - Based on the quantity per shipper mentioned in the 'Header' file of one particular DO,
     No. of shipper would be calculated and print on the label as per the sequence i.e.
     0001/0038
  - GTIN number would be printed on the label as per the GTIN outer indicated in the secondary file
  - SSCC is the unique ID which would be generated by PharmaTrac
  - Based on the consignee lines (Cons Line 1 to Cons line 9) mentioned in the Header file, the data would be printed
  - GTIN barcode with batch and expiry printed based on the Header file. If the shipper contains multiple batches then this barcode would be blank
  - SSSC number which is unique for each container would be printed as mandatory in GS1 specified 1D barcode as well as readable format
- Automatic Print & Apply system affixes the label on the master carton. Sample label as indicated in the below





- Shipper carton validation:
  - A fixed scanner would be mounted just after the P&A to validate the tertiary barcode
  - Stops the conveyor based on the below validations
    - If the barcode is not readable
    - If the barcode is invalid
    - If the barcode is not as per the running batch if same batch is loaded onto the tertiary
    - If the barcode is not as per the running SSCC number if the shipper carton contains multiple batches
  - Against the validation, PharmaTrac updates the shipper carton running count against the DO quantity
- Other features:
  - Facility to re-print and successfully scan the shipper carton
  - Facility to distinguish the reprint shipper cartons in the system
- Temporary barcode for the Shipper carton:
  - Before wrapping process on the conveyor, facility to scan the barcode on the shipper i.e. SSCC ID. This barcode would be used to identify the shipper after the carton wrapping
  - Once the wrapping and strapping is completed, PharmaTrac prints the temporary barcode label – SSCC ID of the shipper
  - Print the temporary barcode label and attach on the wrapped carton



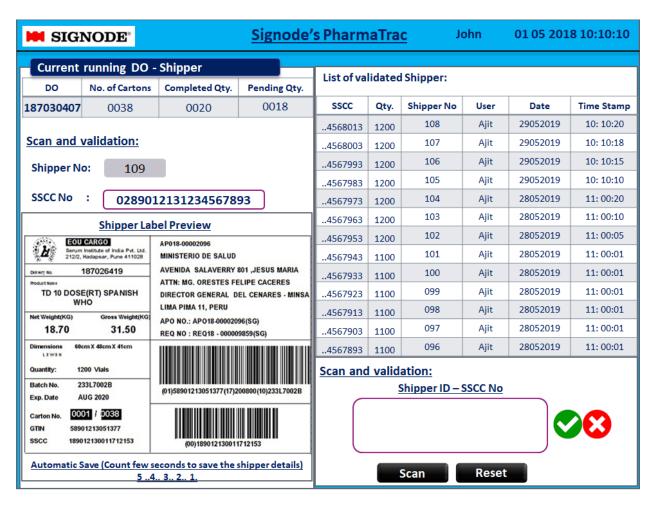


Figure 5. Generation of shipper carton and validation

#### 4.5. Automatic weighment:

- Operator scans the temporary barcode label SSCC ID and displays on the weighment screen
- Application triggers the weigh scales for automatic weighment
- Captures the Gross weight of the Shipper and automatically calculates the tare weight and net weight
- Validates if the weighment is not within the tolerance as per the theoretical weight
- Update the status of the DO with the captured carton weight
- Once all the carton labeling and weighment is completed, update the status of the DO
- DO confirmation to the ERP in the form of .csv file (Signode to SAP) and push it to OUTWARD folder for ERP to fetch for further process
- Below is the format which would be generated and share with SAP

S       187030407       1       1       YF34LSB       0048F111       28901213041902       300       28052019       10 10         S       187030407       1       2       UXPSFHN       0048F111       28901213041902       300       28052019       10 10         S       187030407       1       4       UDYBQXU       0048F111       28901213041902       300       28052019       10 10         T       187030407       1       999       189012130014290498       58901213041903       33.1       28052019       10 10         S       187030407       2       1       LZEGZ2Q       0048F111       28901213041902       300       28052019       10 10         S       187030407       2       2       B4UBQ5       0048F111       28901213041902       300       28052019       10 10	,
S     187030407     1     3     72USSEX     0048F111     28901213041902     300     28052019     10 10       S     187030407     1     4     UDYBQXU     0048F111     28901213041902     300     28052019     10 10       T     187030407     1     999     189012130014290498     58901213041903     33.1     28052019     10 10       S     187030407     2     1     LZEGZQ     0048F111     28901213041902     300     28052019     10 10	14 Ajit
S     187030407     1     4     UDYBQXU     0048F111     28901213041902     300     28052019     10     10       T     187030407     1     999     189012130014290498     58901213041903     33.1     28052019     10     10       S     187030407     2     1     LZEGZZQ     0048F111     28901213041902     300     28052019     10     10	
T 187030407 1 999 189012130014290498 58901213041903 33.1 28052019 10 10 10 10 10 10 10 10 10 10 10 10 10	15 Ajit
S 187030407 2 1 LZEGZ2Q 0048F111 28901213041902 300 28052019 10 10	15 Ajit
	20 Anand
S 187030407 2 2 B4LBQ5 0048F111 28901213041902 300 28052019 10 10	16 Ajit
	17 Ajit
S 187030407 2 3 QRK82T9 0048F111 28901213041902 300 28052019 10 10	17 Ajit
S 187030407 2 4 QEQPPE9 0048F111 28901213041902 300 28052019 10 10	17 Ajit
T 187030407 2 999 189012130014290504 58901213041903 33.2 28052019 10 10	24 Anand

Figure 6. Shipper carton output file

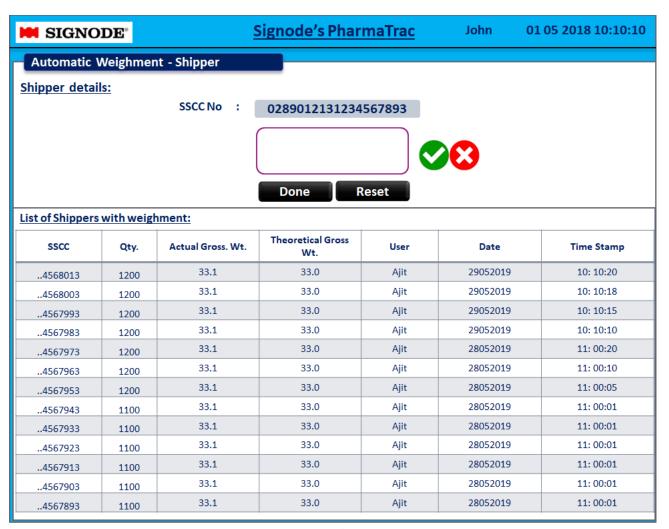


Figure 7. Automatic weighment

#### 4.6. Back track facility:

- PharmaTrac provides the facility to get the complete history of the master carton and box of 300
- UI to display the complete history of the material including
  - o DO receiving
  - DO process start
  - Scanning of Box of 300 validation and reprint if any
  - Shipper carton label printing and label reprint if any
  - Shipper carton validation
  - o Temporary label printing
  - Automatic weighment
  - DO closures and confirmation to ERP



User details with time stamp would be captured against each process

## 4.7. Reports:

- Transaction report to show case list of DOs with status
- Exception report for
  - Invalid box 300 carton and master carton
  - Reprint option for both 300 carton and master carton
  - Weighment exception report
- Day / shift wise reports

## 4.8. Scope of Serum

- Creation of DO and place it in the shared folder created in the Signode PharmaTrac system
- Insert input files and fetch the output files from the shared folder
- Consumables like Labels and Ribbons for Print and Apply Application
- Any ERP licenses required to achieve the integration
- Remote access to Signode system in case of any troubleshooting related to application for immediate solution
- Necessary approvals Safety, electrical, civil, IT etc.
- A desktop PC required for any reports

# 5.0. Sign-Off:

Serum Institute	
Customer Sign-off:	Date:
Name of Customer Representative:	
·	
Title of Customer Representative:	
Title of customer Representative.	
Signode India Limited:	
Signode Sign-off:	Date:
Signode Representative:	

Title of Signode Representative:



#### **Appendix A: Review Comments and Responses:**

### Feedback from Mr. Ajit Gulanikar dated on 30th May 2019

✓ Signode create a shared folder in the PharmaTrac server with a specific naming conversion i.e.

DO with date and serial number

#### Serum - ITD:

There will be a SINGLE shared folder where downloaded files from SAP will be placed. Three files will be download from SAP for each DO and they will be named as HEAD-<dono>, BATCH-<dono>, SECONDARY-<dono>

Note: In SRS please include specimen of these 3 files which we have provided to you

Signode response: Included the files in the section 4.2

✓ ERP has to fetch the DO confirmed file for further processing 
● Delete the DO file once the SAP fetches

Serum - ITD: Don't understand this - can we remove it?

Signode: Modified the sentence and as below

- PharmaTrac places the file in the shared folder and SAP has to fetch the DO which contains the additional fields like captured weight, Time stamp, user details etc.
- DO files would be deleted from the folder for every certain period of time
- ✓ Alternate process to input the Serial Number of the secondary carton

Serum – ITD: Don't understand this – does this mean that we will be allowed to manually enter the UID in case the scan does not work on the 2D code?

Signode: PharmaTrac will have a facility to enter the UID of the box incase the 2D code is not readable

✓ Sequence of the batch and sequence of the box

Confirms that the batch sequence is in same order as that in the SECONDARY-<dono> file

First digit: 2 - This is digit is for the 'extension' which is allotted to Signode

Change first digit from 2 to 3 – we have allotted 2 to another line

Signode: Changed from 2 to 3



✓ Quantity would be printed on the based on the 'Quantity per shipper' which is mentioned in the Header file of one particular DO

Serum – ITD: Quantity would be on basis of quantity from SECONDARY-<dono> of the scanned boxes that go into this shipper

Note – the reason we are 'forcing' scanning of boxes in same order as the SECONDARY-<dono> file is so that the quantity can be derived from there for each shipper . Please speak with us to understand this point. Your sentence seems to indicate that better clarity is needed here

#### Signode:

- Quantity would be printed on the based on the 'Quantity per shipper' which is mentioned in the secondary file of one particular DO. This is based on the actual scanning of the secondary boxes and quantity of each box
- ✓ GTIN barcode with batch and expiry printed based on the Header file. If the shipper contains multiple barcodes then this barcode would be blank

Serum - ITD: Replace the word barcodes with batches

Signode: Changed as below

- GTIN barcode with batch and expiry printed based on the Header file. If the shipper contains multiple batches then this barcode would be blank
- ✓ SSCC number which is unique for each carton would be printed and mandatory filed

Serum - ITD: SSSC number which is unique for each container would be printed as mandatory in GS1 specified 1D barcode as well as readable format

Signode: Changed

✓ Once the wrapping and strapping is completed, PharmaTrac prints the temporary barcode label
 – SSCC ID of the shipper o Print the temporary barcode label and attach on the wrapped carton

Serum – ITD: This is not understood at all – we have already printed and applied the shipper label BEFORE the strapping and plastic cover. What is this 'temporary barcode' ??? Are you planning another label OUTSIDE the plastic wrapping ??

Signode: Yes, we are planning to print one more small barcode as there would be a challenge to read the barcode when it is covered with wrapping material. The typical barcode size is 1 X 2 inch contains the unique ID of the shipper for automatic identification during the weighment.

✓ A desktop PC required for any reports



Serum: Reports will come from your PC only – also SAP GUI client will be loaded on your PC and it will connect to SAP and download the three files for each DO. We do not plan for any PC from our side

Signode: PharmaTrac is a web based application and reports can be accessed within the network.

✓ Gross Weight / Net weight to be printed on shipper (add this point)

Serum – ITD: This would be made on pro-rata basis if the shipper contains less that the standard quantity specified in HEAD-<dono>

Signode: Added the above points in Sec 4.4