# User's Guide Using Transactor Patient Statements

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Transactor has the ability to print a 'Patient Statement' which conforms with the MDD 93/42/EC with minimum fuss.

If your system has already been configured for printing your labs Patient Statements, skip now to Printing Patient Statements 6

If your jobs don't get outsourced to Non-EU labs, you don't need to do anything other than print the Patient Statement. Just see <u>Patient Statements Set Up</u> <sup>2</sup> on how to make your template look the way you want it. This 'default' Patient Statement will contain the simple declaration "..the complete appliance has been wholly manufactured within the EU".

If some or all of your jobs get outsourced to Non-EU labs, then you need to setup manufacturing locations, so that the appropriate ORIGIN code(s) can be added to Jobs. See <u>Setting up Manufacturing Location</u> <u>Origin codes</u> 5

#### Origin of Manufacture

The statement must declare either "..the complete appliance has been wholly manufactured within the EU", or "..not been.." in which case the manufacturing locations must be listed.

By default Transactor will print a Patient Statement with the simple "All within EU" declaration. However if ORIGIN1 or ORIGIN2 codes are found on the job, Transactor will automatically replace this with the "non EU" statement and print the list of manufacturers.

Code.	Description
PATIENT	Anderson, B
SHADE	D7
NOTATION	R 6 L
	6
мв	Maryland / Rochette Bridge
SM	Study Model
ORIGIN1	Zang Chi Dental Lab,21 Block,ZangLang Ind. Pa,Bejing,China
ORIGIN	н

If a lab normally out-sources work to outside the EU then Transactor can be setup to include ORIGIN codes automatically on each job thus saving tedious data entry. If a lab always needs to declare non-EU manufacturing locations, then it may change the background image of the template to contain the required information so that ORIGIN codes don't need to be used.

#### A4 and A5 Templates

- There are 2 templates to choose from. A4 and A5. Both can cater for the simple case (All within EU) or multiple non-EU manufacturing locations.
- The A4 template has space for up to 3 manufacturing locations in the bottom area.
- The A5 statement is more compact with space for up to 2 manufacturing locations.
- The Origin Declaration text can be customised.
- The background image for the form, the other form text, labels and the company logo, can be replaced with the lab's own images.

FATIENT STATEMENT f you haveany queries regarding the ft or performance of your appliance you should contact the prescribing dentist for further information.		High Street Dentai 17 High Street Battle East Sussex TN33 0AE Tel: 01424 777877 Email: support@trant	Laboratory		
Patient's Name		Name of Prescriber	Ginic Name and Addres	s	
Mr Churchill Winst	ton	Mr Tom Beresford BDS	Station Road Dent	al Practice	
Dateof Manufacture		Lab Reference	394 Old London Road, Hastings, Sussex, TN35 5EF Tel: 01424 777877		Sussex, TN35 5EF
15/03/10		A/c 44 - Doc 15337			
Product Code	Descriptio	n/Typeof Appliance		Quantity	Grade
1-3T 1-3 TOOTH DENTURE CL2 CLASP x 2				1	Independent
ORGIN CFM ANUFACTURE DECLARATION This complete appliance has been wholly manufactured within the EU.					
Your attention isdrawn to the and properties specified by relevant essential requirem	Your attention is drawn to the following statement: This is a custom-made medical device that has been manufactured to satisfy the design characteristics and properties specified by the prescriber for the above named patient. This medical device is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex lof the Medical Devices Directive and the United Kingdom Medical Devices Regulations.				
This statement does not apply to medical devices that have been repaired and/or refurbished for an individual patient's use.					

#### Also See:

Patient Statements Set Up 2 Printing Patient Statements 6

MHRA document "Guidance to Changes to the Medical Devices Directive 93/42/EC with respect to custom-made devices statements"

#### Terms:

MHRA: Medicines and Healthcare products Regulatory Agency MD Directive: Medical Devices Directive. The Medical Devices Directive covers the regulatory requirements of the European Union for Medical Devices.

### Patient Statements Set Up

This topic will guide you through setting up an A4 Patient Statement.

#### To invoke the Printout Type Properties for the Patient Statement

- From the Tools menu, choose Printing Setup Printout Type Properties
- In Printout Type, choose Patient Statement (A4).. (or A5)

Printout Type       Page Format         Patient Statement (A4)       A4 210 x 297 mm         Credit Note (A4)       Choose Patient Statement         Delivery Note to Practice (Ai)       Choose Patient Statement         Delivery Note to Practice (A)       Descent to Practice (A)         Delivery Note to Practice (Bin)       Delivery Note to Practice (Bin)         Delivery Note to Practice (Bin)       A4 (or A5)         Delivery Note (A5)       Delivery Note (A5)         Query Document       Job Ticket (A4)         Job Ticket (Label)       0         Quote       Pictures         Patient Statement (A4)       Pictures         Statement (adat range)       Statement (adat range)         Statement (unpaid invoices)       Address Labels         Practice Summay (date range)       Picture files should be located in the trans(1/lab/exe folder.         Practice Summary (date range)       Picture dwithin the EU. This complete appliance has not been wholly manufactured         Booked in Items       File name & extension of (bn D to lobe (n D ate)         Booked in Items       File name & extension of (bn D to lobe (n D ate)         Booked in Items       File name & extension of (bn D to lobe (n D ate)         Booked in Items       File name & extension of (bn D to lobe (n D ate)         Booked In Items

### To change the Declaration Statement

- In the Printout Type Properties
- Change the text in the Message area
- Choose Close



There are two messages encoded in this box. By default a Patient Statement will be printed with the first simple "All within EU" declaration. This is the text before the ^ Divider as shown in the above image.

The second "non-EU" message is the one Transactor will print if ORIGIN1 or ORIGIN2 codes are found on the job, along the list of manufacturers. NB: even if your lab currently does not out-source outside the EU, you can leave this second message intact, it just won't be used. See below.

### To change the company logo

#### Preparation

place your company's logo image file into the C:\tran61\lab\exe folder on your PC. The file type must be either bitmap (.BMP) or Windows Meta File (.WMF). The filename must be less than 8 characters with no spaces so for simplicity rename your file to logo.bmp or logo.wmf. The image should have been supplied by

your graphics designer as a high quality graphic to the correct intended size. With the correct logo file you should have pin-sharp printouts indistinguishable from pre-printed stationery.

- In the Printout Type Properties
- In the Pictures group box, enter the logo's file name (eg. Logo.bmp) into the box below the one containing PForm.wmf.
- Enter approximate X and Y position pixel values (about 100 = 1CM) from the top left of the paper to the top left of the logo. You will need to experiment to get this right.
- Choose Close

Print a Patient statement to the Preview Window to see your logo's positioning and go back to Printout Type Properties to adjust your X and Y values until correct.



#### To add or change the background image

#### Preparation

The default image (PForm.wmf) is already located in in the C:\tran61\lab\exe folder on your PC. Your graphics designer may modify this or produce another. The file type must be either bitmap (.BMP) or Windows Meta File (.WMF). The filename must be less than 8 characters with no spaces so for simplicity rename your file to PForm2.bmp or PForm2.wmf. The image should have been supplied by your graphics designer as a high quality graphic to the correct intended size.

- In the Printout Type Properties
- In the Pictures group box, enter the new background image file name (eg. PForm2.bmp) into the upper box currently containing PForm.wmf.
- Choose Close

Print a Patient statement to the Preview Window to see your new background image's positioning and go back to Printout Type Properties to adjust your X and Y values until correct.

#### To configure printing a Patient Statement automatically on Book Out

- From the Tools Menu, choose Printing Setup Printing on Confirm Action
- Add Patient Statement (A4 or A5) to the Printout Type list
- On the required check boxes in the correct row and choose the Output and number of copies.

ι	Isual printing when Actioning	g document	s from this PC	×
	Printout Type	Condition	Action Output To	Copies
			Book In Job Book Out Job Ongoing Book Out Job Charge Finalise Credit Note Hold/Quote Job Hold Query Finalise Query Print Document Despatch Back Orders	
	Job Ticket (A4)	-		▼ 1 copy ▼
	Invoice (A4)	-	Batch Queue	▼ 1 copy ▼
	Credit Note (A4)	-		▼ 1 copy ▼
	Delivery Note to Practice (A4)	-		▼ 2 copies ▼
	Patient Statement (A4)	-		▼ 1 copy ▼
	<b></b>	-	Prompt to Print Patient Statement	
1	-	-	Con Action Book Out Ongoing, or	
			book out charge	

- Click Close
- When you book a job out in future, you will be automatically prompted to print a Patient Statement

#### Also See: <u>Setting up Manufacturing Location Origin codes</u> <u>Printing Patient Statements</u> Setting up Manufacturing Location Origin codes

If your lab uses other Non-EU laboratories for all or part of the manufacturing process, then these need to be listed on the Patient Statement for the job that it concerns.

This is done by adding a product lineitem onto the job, with a code of ORIGIN1 or ORIGIN2 etc. Each manufacturer must have an individual origin code. The presence of an ORIGIN code on the job will signal Transactor to use the Non-EU declaration and list the manufacturers on the Patient Statement.

### To add or change Origin codes for other Manufacturing locations

- On a Main Form, blank or a job being modified, click in the Code column and press ENTER.
- In the Products and Services dialog, in the 'Find by Code' box, enter ORIGIN1
- In the State box, choose NOTE

Code.				Description	
	Products	and Services			
	Eind by Code	RIGIN1	Find	State NOTE	\ ·
		C Description		Price NHS	
					Choose Note
				Ļ	

Note: If ORIGIN1 already exists this will be listed so just right click it, choose Properties and check the details are correct, then skip the rest of this topic.

- Click 'Add New'
- Enter the manufacturing location (name and short address). There are limited characters so you may need to abbreviate\*
- Choose OK and then Select Onto Form (to verify it looks ok on the form).

Code.	Description		
PATIENT	Anderson, B		
SHADE	D7		
NOTATION	R 6 L		
	6		
мв	Maryland / Rochette Bridge		
SM	Study Model		
ORIGIN1	Zang Chi Dental Lab,21 Block,ZangLang Ind. Pa,Bejing,China		
ORIGIN	1		

That's it. You now have the ability to 'register' other 'Non-EU' manufacturing locations involved with the Job and your Patient Statement will reflect this fact.

Also see Printing Patient Statements

### **Printing Patient Statements**

#### To Print a Patient Statement

- On a Main Form, select a previously Booked Out job
- Click the Printer Icon on the Tool Bar, or choose Action Print (F5)

Confirm Action	
?	Print Document 🖨
	Issue printout request(s) for the current document
Output	
Patient Statement (A4)	▼ To Printer ▼ 1 copy ▼

• In the Output group, choose Patient Statement (A4) or (A5) to Printer or Preview.

FATIENT STATEMENT fyou haveany queries regarding the fit or performance of your appliance you should contact the prescribing dentist for further information.		High Street Denta 17 High Street Battle East Sussex TN33 0AE Tel: 01424 777877 Email: support@tran	I Laboratory sactor.co.uk	
	Name of Prescriber	Ginic Name and Addres	s	
Winston	Mr Tom Beresford BDS	Station Road Den	tal Practice	
	Lab Reference	394 Old London Road, Hastings, Sussex, TN35 5EF Tel: 01424 777877		s, Sussex, TN35 5EF
10	A/c 44 - Doc 15337			
Description	on/Typeof Appliance		Quantity	Grade
1-3T 1-3 TOOTH DENTURE CL2 CLASP x 2			1	Independent
CRGIN OF MANUFACTURE DECLARATION This complete appliance has been wholly manufactured within the EU.				
Your attention is drawn to the following statement: This is a custom-made medical device that has been manufactured to satisfy the design characteristics and properties specified by the prescriber for the above named patient. This medical device is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex1 of the Medical Devices Directive and the United Kingdom Medical Devices Regulations.				
	PATIENT rise regarding the rise regarding the Winston TO Description CLA Into the following ied by the prescription is a rescription is a resc	PATIENT STATEMENT  rise regarding the ft or performance of your appliance you fact the prescribing dentist for further information.            Name of Prescriber           Winston         Mr Tom Beresford BDS           Lab Reference         10           10         A/c 44 - Doc 15337           Description/Typeof Appliance         1-3 TOOTH DENTURE           CLASP x 2         ORGIN OF MANUFACTURE	PATIENT STATEMENT       High Street Denta 17 High Street Battle         rise regarding the ft or performance of your appliance you tact the prescribing dentist for further information.       Tel: 01424 777877 Email: support@trant         Name of Prescriber       Olinic Name and Address         Winston       Mr Tom Beresford BDS         Station Road Den 10       A/c 44 - Doc 15337         Description/Typeof Appliance       Station Road Den 394 Old London R Tel: 01424 77787         Description/Typeof Appliance       Station Road Den 394 Old London R Tel: 01424 77787         Description/Typeof Appliance       CLASP x 2         ORGIN OF MANUFACTURE CLASP x 2       CRGIN OF MANUFACTURE DELARATION         This complete appliance has been wholly manufactured within into the followingstatement: This is a custom-made medical device that has been manual devices that has been manual dev	PATIENT STATEMENT       High Street Dental Laboratory 17 High Street Battle         East Sussex       TN33 0AE         rise regarding the ft or performance of your appliance you fact the prescribing dentist for further information.       This 01424 777877         Email: support@transactor.co.uk       Marre of Prescriber       Clinic Name and Address         Winston       Mr Tom Beresford BDS       Station Road Dental Practice         10       A/c 44 - Doc 15337       Station Road Dental Practice         201424 777877       Email: support@transactor.co.uk         10       A/c 44 - Doc 15337       Quantity         10       A/c 44 - Doc 15337       Quantity         10       A/c 44 - Doc 15337       Quantity         13 TOOTH DENTURE       1       1         1-3 TOOTH DENTURE       1       1         1       1       1         CRGIN CFMANUFACTUREDELARATION         This complete appliance has been wholy manufactured within the EU.         Into the following statement: This is a custom-made medical device that has been manufactured to surface of the Medical Devices Directive and the United Kingdom Medical Devices Directive and the United King ton Medical Devices Directive and the United

### To Print a Patient Statement automatically on Book Out

This assumes you have set up printing on confirm action. See Patient Statements Set Up 4

- On a Main Form, select a previously Booked Out job
- Click the Printer Icon on the Tool Bar, or choose Action Print (F5)

Confirm Action		×
🤣 В	ook Out Job Charge 📴	Doc No: 1387
Save the Output Delivery Note to Practice (A4) Patient Statement (A4)	current job as 'Booked Out Charged' and set invoice date     To Printer ▼ 1 copy ▼     To Printer ▼ 1 copy ▼	

### To Print a Patient Statement with Non-EU Manufacturing Locations

This assumes you have set up one or more ORIGIN codes. See <u>Setting up Manufacturing Location Origin</u> <u>codes</u>

 On a Job being modified, in a blank row in the lineitem area, enter ORIGIN1 in the code column and press ENTER

Code.	Description
PATIENT	Anderson, B
SHADE	D7
NOTATION	R 6 L
	6
мв	Maryland / Rochette Bridge
SM	Study Model
ORIGIN1	Zang Chi Dental Lab,21 Block,ZangLang Ind. Pa,Bejing,China
	1

- Book out the job as usual
- In the Confirm Action dialog, in the Output group ensure Patient Statement (A4 or A5) is selected as one of the documents to be printed
- Choose OK

PATIENT STATEMENT If you have any queries regarding the fit or performance of your appliance you should contact the prescribing dentist for further information.		DentaLab l 17 High Str Battle East Susse: TN33 0AE Tel: 0142477: Email: sales@	Limited eet X 5007 transactor.co.uk		
Pati ent's Name		Name of Prescriber	a	inic Name an	d Address
B Anderson	Mr P Kelly BDS Ro 69 Ro E2 Th Te		Robertsbrid 69 High Stre Robertsbrid East Susse TN32 5AP Tel: 01580 1	ge Dental Su set ge x 123457	ırgery
	Date of N	fanufacture		Lab Refere	ince
	17/03	3/10	A/c 295 - Doc 1387		
Product Code	Descri	ttion/Typeof Appliance		Quantity	Grade
MB SM	Mary Stud	land / Rochette Bridge y Model		1	NHS Other Non-EU manufacturing locations listed here
		ORIGIN OF MANUFACT	UREDECLARATION		
This complete appliance has not been wholly manufactured within the EU. Other Manufacturing locations are:					
ORIGIN1	ORIGIN1 Zang Chi Dental Lab,21 Block,ZangLang Ind. Pa,Bejing,China				
Your attention is drawn to the following statement: This is a custom-mademedical device that has been manufactured to satisfy the design characteristics and properties specified by the prescriber for the above named patient. This medical device is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex1 of the Medical Devices Directive and the United Kingdom Medical Devices Regulations. This determent does not acredy to medical devices that have been repaired and corretuitished for an individual national succession.					

By the way, the ORIGIN codes you see on Transactor's Main Form won't be printed in the items area of the Patient Statement. Transactor picks up these details and puts them neatly into your Declaration List. Clever stuff don't you think. See <u>Printing Patient Statements</u> of for a example print out.

There's more things you can do to optimize your process and save repetitive typing. You can decide whether to manually add the ORIGIN product code onto Jobs as and when required, or to setup Jobs so that one or more ORIGIN codes are automatically on new jobs. See <u>New Document Setup</u> 10

### New Document Setup

You can configure **Transactor** to automatically have a certain layout on the screen when a new job is started. Any of your existing predefined Line Notes can be made to appear in the new job.

Choose New Document Setup... from the Tools menu.

New Document Setup	×
When starting a New Job The following LINE NOTES will be added:	
PATIENT  SHADE  NOTATION  R	L
	Apply Close

From here you can customise the level of pre-set details you want to record with each :

- New Job
- New Credit Note
- New Query

You can specify up to 6 line notes that will be automatically added to a new blank document (ie. when you choose *Action... New Job, New Credit Note* or *New Query*).

Select the line notes from the dropdown lists. To remove a selection, choose the blank entry at the top of the list.

### Website Contact Us

#### www.transactor.co.uk

### Telephone sales & technical support

Telephone technical support is available only to new customers in the trial period, and Premium Support customers.

01424 777877

### Write or visit

## Contact Us

Pearce & Robinson LTD 17 High Street, Battle, Sussex TN33 0AE Tel: 01424 777877

#### NOTES

Sales & Support Telephone Mon-Fri 0900-1700hrs excl. Bank Holidays. After your free Premium Support period is up you can purchase 12 months renewal from <u>www.</u> <u>transactor.co.uk</u>

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