

RAYNAUD'S ATTACK BOOKLET

Your Initials _____

Your ID Number _____

Date this Booklet First Used _____ - _____ - _____

RAYNAUD'S ATTACK CARD

Your ID Number: _____ - _____ - _____

Date: _____ - _____ - _____
Month Day Year

No attacks occurred:

Time of beginning of attack: _____ : _____ AM PM ALLTIME
Hours Minutes (Circle)

Color Rectangle Number that looks most like my most affected finger: 1 2 3 4 5 6 7 8 9 FINGER
(Please circle one)

Hand Picture Letter that looks most like my hand: A B C D E F HAND_LTR
(Please circle one)

DAILY DIARY

Please complete one page of this diary each day of the week. Return the completed diary to the medical staff at your Raynaud's Treatment Center.

ID No.				
Form Type	P	D		

1. Day 1

A. Your initials: - - - - -

B. Today's date: - - - - - F10 DAYS
 Month Day Year

(1) Time of completing this page: - - - - - : - - - - - () ()
 AM PM
 ACTION

C. Did you take action to stop or prevent an attack today? - - - - - () ()
 Yes No

What action did you take? (Check all that apply.)

A. Moved to another location - - - - - MOVED ()

B. Put on more clothing (hat, sweater(s), gloves, coat(s), etc) CLOTH ()

C. Adjusted the thermostat - - - - - ADJTEMP ()

D. Other action - - - - - DTHR ()

Please describe: _____

D. Did your attacks, or your concern about having attacks, cause you to change what you were doing today? (Check one answer.) CHANGE

Never - - - - - ()

Occasionally - - - - - ()

Often - - - - - ()

Always - - - - - ()

E. How many attacks did you have today? - - - - - NBR-ATT

If 0 attacks, do not answer remaining questions on this page.

F. Length of attacks in minutes: LONG MIN

(1) How long was your longest attack today? - - - - - minutes

(2) How long was your shortest attack today? - - - - - SHORT MIN

(3) What was the average length of your attacks today? - - - - - AVMN minutes

G. What average pain or discomfort level was associated with the attacks you experienced today? (Check one answer.) PAIN

None - - - - - ()

Mild - - - - - ()

Moderate - - - - - ()

Severe - - - - - ()

ID No.				
Form Type	P	D		

2. Day 2

A. Today's date: - - - - -
Month Day Year

(1) Time of completing this page: - - - - - : (1) (2)
AM PM

B. Did you take action to stop or prevent an attack today? - - - - - (1) (2)
Yes No

What action did you take? (Check all that apply.)

A. Moved to another location - - - - - (1)

B. Put on more clothing (hat, sweater(s), gloves, coat(s), etc) - - - - (1)

C. Adjusted the thermostat - - - - - (1)

D. Other action - - - - - (1)

Please describe: _____

C. Did your attacks, or your concern about having attacks, cause you to change what you were doing today? (Check one answer.)

Never - - - - - (1)

Occasionally - - - - - (2)

Often - - - - - (3)

Always - - - - - (4)

D. How many attacks did you have today? - - - - - _____

If 0 attacks, do not answer remaining questions on this page.

E. Length of attacks in minutes:

(1) How long was your longest attack today? - - - - - _____
minutes

(2) How long was your shortest attack today? - - - - - _____
minutes

(3) What was the average length of your attacks today? - - - - - _____
minutes

F. What average pain or discomfort level was associated with the attacks you experienced today? (Check one answer.)

None - - - - - (1)

Mild - - - - - (2)

Moderate - - - - - (3)

Severe - - - - - (4)

ID No.		-			
Form Type	P	D			

3. Day 3

A. Today's date: - - - - - / /
Month Day Year

(1) Time of completing this page: - - - - - : (1) (2)
AM PM

B. Did you take action to stop or prevent an attack today? - - - - - (1) (2)
Yes No

What action did you take? (Check all that apply.)

A. Moved to another location - - - - - (1)

B. Put on more clothing (hat, sweater(s), gloves, coat(s), etc) - - - - (1)

C. Adjusted the thermostat - - - - - (1)

D. Other action - - - - - (1)

Please describe: _____

C. Did your attacks, or your concern about having attacks, cause you to change what you were doing today? (Check one answer.)

Never - - - - - (1)

Occasionally - - - - - (2)

Often - - - - - (3)

Always - - - - - (4)

D. How many attacks did you have today? - - - - -

If 0 attacks, do not answer remaining questions on this page.

E. Length of attacks in minutes:

(1) How long was your longest attack today? - - - - - minutes

(2) How long was your shortest attack today? - - - - - minutes

(3) What was the average length of your attacks today? - - - - - minutes

F. What average pain or discomfort level was associated with the attacks you experienced today? (Check one answer.)

None - - - - - (1)

Mild - - - - - (2)

Moderate - - - - - (3)

Severe - - - - - (4)

ID No.		-			
Form Type	P	D			

4. Day 4

A. Today's date: - - - - - _____
Month Day Year

(1) Time of completing this page: - - - - - _____:_____
(1) (2)
AM PM

B. Did you take action to stop or prevent an attack today? - - - - - (1) (2)
Yes No

What action did you take? (Check all that apply.)

A. Moved to another location - - - - - (1)

B. Put on more clothing (hat, sweater(s), gloves, coat(s), etc) - - - - (1)

C. Adjusted the thermostat - - - - - (1)

D. Other action - - - - - (1)

Please describe: _____

C. Did your attacks, or your concern about having attacks, cause you to change what you were doing today? (Check one answer.)

Never - - - - - (1)

Occasionally - - - - - (2)

Often - - - - - (3)

Always - - - - - (4)

D. How many attacks did you have today? - - - - - _____

If 0 attacks, do not answer remaining questions on this page.

E. Length of attacks in minutes:

(1) How long was your longest attack today? - - - - - _____ minutes

(2) How long was your shortest attack today? - - - - - _____ minutes

(3) What was the average length of your attacks today? - - - - - _____ minutes

F. What average pain or discomfort level was associated with the attacks you experienced today? (Check one answer.)

None - - - - - (1)

Mild - - - - - (2)

Moderate - - - - - (3)

Severe - - - - - (4)

ID No.					
Form Type	F	D			

5. Day 5

A. Today's date: - - - - - / /
Month Day Year

(1) Time of completing this page: - - - - - : (1) (2)
AM PM

B. Did you take action to stop or prevent an attack today? - - - - - (1) (2)
Yes No

What action did you take? (Check all that apply.)

A. Moved to another location - - - - - (1)

B. Put on more clothing (hat, sweater(s), gloves, coat(s), etc) - - - - (1)

C. Adjusted the thermostat - - - - - (1)

D. Other action - - - - - (1)

Please describe: _____

C. Did your attacks, or your concern about having attacks, cause you to change what you were doing today? (Check one answer.)

Never - - - - - (1)

Occasionally - - - - - (2)

Often - - - - - (3)

Always - - - - - (4)

D. How many attacks did you have today? - - - - -

If 0 attacks, do not answer remaining questions on this page.

E. Length of attacks in minutes:

(1) How long was your longest attack today? - - - - - minutes

(2) How long was your shortest attack today? - - - - - minutes

(3) What was the average length of your attacks today? - - - - - minutes

F. What average pain or discomfort level was associated with the attacks you experienced today? (Check one answer.)

None - - - - - (1)

Mild - - - - - (2)

Moderate - - - - - (3)

Severe - - - - - (4)

ID No.		-				
Form Type	F	D				

6. Day 6

A. Today's date: - - - - -
Month Day Year

(1) Time of completing this page: - - - - - : (1) (2)
AM PM

B. Did you take action to stop or prevent an attack today? - - - - - (1) (2)
Yes No
↓

What action did you take? (Check all that apply.)

A. Moved to another location - - - - - (1)

B. Put on more clothing (hat, sweater(s), gloves, coat(s), etc) - - - - (1)

C. Adjusted the thermostat - - - - - (1)

D. Other action - - - - - (1)

Please describe: _____

C. Did your attacks, or your concern about having attacks, cause you to change what you were doing today? (Check one answer.)

Never - - - - - (1)

Occasionally - - - - - (2)

Often - - - - - (3)

Always - - - - - (4)

D. How many attacks did you have today? - - - - -
↓

If 0 attacks, do not answer remaining questions on this page.

E. Length of attacks in minutes:

(1) How long was your longest attack today? - - - - -
minutes

(2) How long was your shortest attack today? - - - - -
minutes

(3) What was the average length of your attacks today? - - - - -
minutes

F. What average pain or discomfort level was associated with the attacks you experienced today? (Check one answer.)

None - - - - - (1)

Mild - - - - - (2)

Moderate - - - - - (3)

Severe - - - - - (4)

ID No.		-		
Form Type	P	D		

7. Day 7

A. Today's date: - - - - - - -
Month Day Year

(1) Time of completing this page: - - - - - : () ()
AM PM

B. Did you take action to stop or prevent an attack today? - - - - - () ()
Yes No

What action did you take? (Check all that apply.)

A. Moved to another location - - - - - ()

B. Put on more clothing (hat, sweater(s), gloves, coat(s), etc) - - - - ()

C. Adjusted the thermostat - - - - - ()

D. Other action - - - - - ()

Please describe: _____

C. Did your attacks, or your concern about having attacks, cause you to change what you were doing today? (Check one answer.)

Never - - - - - ()

Occasionally - - - - - ()

Often - - - - - ()

Always - - - - - ()

D. How many attacks did you have today? - - - - -

If 0 attacks, do not answer remaining questions on this page.

E. Length of attacks in minutes:

(1) How long was your longest attack today? - - - - - minutes

(2) How long was your shortest attack today? - - - - - minutes

(3) What was the average length of your attacks today? - - - - - minutes

F. What average pain or discomfort level was associated with the attacks you experienced today? (Check one answer.)

None - - - - - ()

Mild - - - - - ()

Moderate - - - - - ()

Severe - - - - - ()

ID No.					
Form Type	P	D			

The following will be completed by medical staff.

8. Research Coordinator:

Signature: _____

RTS Staff No: _____

9. Data form reviewed : _____

Month Day Year

ID No.		-			
Form Type	P	D			

ATTACK BOOKLET SUMMARY FORM

ID No.		-			
Form Type	A	B			

PART I: VISIT IDENTIFICATION

1. Patient's initials:
2. Date Attack Card Booklet (Form 08) started:
Month Day Year

PART II: INFORMATION FROM ATTACK CARD BOOKLET (FORM 08)

	Date			No Attacks on This Day	Time Attack Began ATT. TIME	AM	PM	Color FINGER	Hand HAND
	Month	Day	Year						
3.	() :	()	()
4.	() :	()	()
5.	() :	()	()
6.	() :	()	()
7.	() :	()	()
8.	() :	()	()
9.	() :	()	()
10.	() :	()	()
11.	() :	()	()
12.	() :	()	()
13.	() :	()	()
14.	() :	()	()
15.	() :	()	()
16.	() :	()	()
17.	() :	()	()
18.	() :	()	()

	Date			No Attacks	Time Attack Began	AM	PM	Color	Hand
	Month	Day	Year	on This Day					
19.	() :	()	()
20.	() :	()	()
21.	() :	()	()
22.	() :	()	()
23.	() :	()	()
24.	() :	()	()
25.	() :	()	()
26.	() :	()	()
27.	() :	()	()
28.	() :	()	()
29.	() :	()	()
30.	() :	()	()

PART III: ADMINISTRATIVE MATTERS

31. Research Coordinator: Signature:

RTS Staff No.:

32. Date form completed:

ID No.		-			
Form Type	A	B			

FORMS 08, 10 (Rev. 1), 26 (Rev. 0)
 ONE RECORD PER SUBJECT PER DAY
 ATT_DAY.SSD

<u>FORM</u>	<u>ITEM*</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
		NEWID	I(4)	
8/26	CALC	ANYATTK	I(2)	No. of ATTACKS in a day
8/26	CALC	VERIFIED	I(2)	No. of VERIFIED attacks in a day
10	B	F10_DAYS	I(4)	Date on Form 10 Days from randomization
	CALC	PERIOD	CHAR(2)	BL = Baseline M2 = After randomization Y1 = 1 year
10	C	ACTION	I(1)	} 1 = Yes, 2 = No
	CA	MOVED	I(1)	
	CB	CLOTH	I(1)	
	CC	ADJTEMP	I(1)	
	CD	OTHR	I(1)	
10	D	CHANGE	I(1)	1 = Never 2 = Occasionally 3 = Often 4 = Always
10	E	NBR_ATT	I(2)	No. of attacks in a day
10	F	LONG_MIN	I(3)	} Minutes
	F2	SHRT_MN	I(3)	
	F3	AVMN	I(3)	
10	G	PAIN	I(1)	1 = None 2 = Mild 3 = Moderate 4 = Severe

*CALC denotes a variable that is computed in the SAS program. This variable is not on any form.

FORMS 08, 10 (Rev. 1), 26 (Rev. 0)

ONE RECORD PER ATTACK (OR PER DAY IF NO ATTACKS RECORDED)

ATT_EACH.SSD

<u>FORM</u>	<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
		NEWID	I(4)	
10	B	F10_DAYS	I(4)	Date on Form 10 Days from randomization
10	CALC	PERIOD	CHAR(2)	BL = Baseline M2 = After Randomization Y1 = 1 Year
8/26		ATT_TIME	HH:MM	Time of Attack (Military)
8/26	CALC	ANY_ATT	I(1)	1 = Any Attack 0 = No Attack
8/26	CALC	VER_ATT	I(1)	1 = Verified Attack 0 = No Attack
8/26		FINGER	I(1)	1 - 9 Finger Code
8/26		HAND_LTR	CHAR(1)	A - F Hand Pattern Code

FORMS 08, 10 (Rev. 1), 26 (Rev. 0)

ONE RECORD PER SUBJECT PER PERIOD
ATT_PER.SSD

<u>VARIABLE</u>	<u>DESCRIPTION</u>
NEWID	
PERIOD	BL = Baseline M2 = After randomization Y1 = 1 year

OUTCOMES BASED ON FORM 10

DAY_F10	Days used in calculations
ATT_F10	Attacks reported
RATE_F10	Attack rate (attacks/day)
LOGR_F10	LN(attack rate)

OUTCOMES BASED ON ATTACK CARDS

DAY_AAC	Days used in calculations
ATT_AAC	Attacks reported
RATE_AAC	Attack rate (attacks/day)
LOGR_AAC	LN(attack rate)
DAY_VAC	Days used in verified calculations
ATT_VAC	Verified attacks reported
RATE_VAC	Verified attack rate (attacks/day)
LOGR_VAC	LN(verified attack rate)

CONTENTS PROCEDURE

Data Set Name:	RTS.ATT_DAY	Observations:	22010
Member Type:	DATA	Variables:	16
Engine:	V612	Indexes:	0
Created:	11:06 Thursday, April 27, 2000	Observation Length:	70
Last Modified:	11:06 Thursday, April 27, 2000	Deleted Observations:	0
Protection:		Compressed:	NO
Data Set Type:		Sorted:	NO
Label:			

-----Engine/Host Dependent Information-----

Data Set Page Size:	8192
Number of Data Set Pages:	191
File Format:	607
First Data Page:	1
Max Obs per Page:	116
Obs in First Data Page:	83

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos	Format	Label
ff						
1	ACTION	Num	4	0		f10qc Action to prevent/stop attack
4	ADJTEMP	Num	4	12		f10qcd Adjusted the thermostat
14	ANYATTK	Num	4	50		Attack cards -- ANY attacks
10	AVMN	Num	4	36		f10qf3 Average length (min)
6	CHANGE	Num	4	20		f10qd Attacks changed plans
3	CLOTH	Num	4	8		f10qcb Put on more clothing
16	F10_DAYS	Num	8	62	4.	f10qb Diary date
8	LONG_MN	Num	4	28		f10qf1 Longest attack (min)
2	MOVED	Num	4	4		f10qca Moved to another location
7	NBR_ATT	Num	4	24		f10qe Number of attacks
15	NEWID	Num	8	54	4.	Patient ID
5	OTHR	Num	4	16		f10qcd Other action
11	PAIN	Num	4	40		f10qg Average pain
12	PERIOD	Char	2	44		Data collection period
9	SHRT_MN	Num	4	32		f10qf2 Shortest attack (min)
13	VERIFIED	Num	4	46		Attack cards -- VERIFIED attacks

CONTENTS PROCEDURE

Data Set Name:	RTS.ATT_EACH	Observations:	29874
Member Type:	DATA	Variables:	8
Engine:	V612	Indexes:	0
Created:	11:06 Thursday, April 27, 2000	Observation Length:	39
Last Modified:	11:06 Thursday, April 27, 2000	Deleted Observations:	0
Protection:		Compressed:	NO
Data Set Type:		Sorted:	NO
Label:			

-----Engine/Host Dependent Information-----

Data Set Page Size:	8192
Number of Data Set Pages:	144
File Format:	607
First Data Page:	1
Max Obs per Page:	208
Obs in First Data Page:	175

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos	Format	Informat	Label
5	ANY_ATT	Num	4	17			Attack cards -- ANY attack
3	ATT_TIME	Num	8	5	HHMM		Time of attack (military)
8	F10_DAYS	Num	8	31	4.		f10qb Diary date
1	FINGER	Num	4	0	1.	BEST22.	Color of Fingers
2	HAND_LTR	Char	1	4			Pattern of Color
7	NEWID	Num	8	23	4.		Patient ID
6	PERIOD	Char	2	21			Data collection period
4	VER_ATT	Num	4	13			Attack cards -- VERIFIED attack

CONTENTS PROCEDURE

Data Set Name:	RTS.ATT_PER	Observations:	811
Member Type:	DATA	Variables:	14
Engine:	V612	Indexes:	0
Created:	11:06 Thursday, April 27, 2000	Observation Length:	106
Last Modified:	11:06 Thursday, April 27, 2000	Deleted Observations:	0
Protection:		Compressed:	NO
Data Set Type:		Sorted:	NO
Label:			

-----Engine/Host Dependent Information-----

Data Set Page Size:	8192
Number of Data Set Pages:	11
File Format:	607
First Data Page:	1
Max Obs per Page:	77
Obs in First Data Page:	57

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos	Format	Label
ff						
7	ATT_AAC	Num	8	42	3.	No. of attacks from ANY attack card
5	ATT_F10	Num	8	26	3.	No. of attacks from Form 10
6	ATT_VAC	Num	8	34	3.	No. of attacks from VERIFIED attack card
10	DAY_AAC	Num	8	66	2.	Days available from ANY attack card
8	DAY_F10	Num	8	50	2.	Days available from Form 10
9	DAY_VAC	Num	8	58	2.	Days available from VERIFIED attack card
13	LOGR_AAC	Num	8	90	5.2	LN(attack rate) from ANY attack card
11	LOGR_F10	Num	8	74	5.2	LN(attack rate) from Form 10
12	LOGR_VAC	Num	8	82	5.2	LN(attack rate) from VERIFIED attack crd
14	NEWID	Num	8	98	4.	Patient ID
1	PERIOD	Char	2	0		Data collection period
4	RATE_AAC	Num	8	18	5.2	Attack rate from ANY attack card
2	RATE_F10	Num	8	2	5.2	Attack rate from Form 10
3	RATE_VAC	Num	8	10	5.2	Attack rate from VERIFIED attack card

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
ACTION	f10qc Action to prevent/stop attack	21903	1.5	0.5	1.0	2.0
MOVED	f10qca Moved to another location	21903	1.9	0.3	1.0	8.0
CLOTH	f10qcb Put on more clothing	21903	1.6	0.5	1.0	2.0
ADJTEMP	f10qcd Adjusted the thermostat	21903	1.8	0.4	1.0	8.0
OTHR	f10qcd Other action	21903	1.8	0.4	1.0	8.0
CHANGE	f10qd Attacks changed plans	22010	1.4	0.9	1.0	8.0
NBR_ATT	f10qe Number of attacks	21951	0.8	1.2	0.0	30.0
LONG_MN	f10qf1 Longest attack (min)	9170	31.4	46.6	0.0	780.0
SHRT_MN	f10qf2 Shortest attack (min)	9158	21.9	37.5	0.0	780.0
AVMN	f10qf3 Average length (min)	8993	26.2	40.2	0.0	780.0
PAIN	f10qg Average pain	9129	2.2	0.7	1.0	8.0
VERIFIED	Attack cards -- VERIFIED attacks	21727	0.5	0.9	0.0	8.0
ANYATTK	Attack cards -- ANY attacks	21746	0.8	1.2	0.0	10.0
NEWID	Patient ID	22010	156.7	90.4	1.0	313.0
F10_DAYS	f10qb Diary date	22010	145.9	188.8	-120.0	510.0

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
FINGER	Color of Fingers	17042	2.7	2.3	0.0	9.0
ATT_TIME	Time of attack (military)	17004	48183.8	17593.6	0.0	86100.0
VER_ATT	Attack cards -- VERIFIED attack	29565	0.4	0.5	0.0	1.0
ANY_ATT	Attack cards -- ANY attack	29602	0.6	0.5	0.0	1.0
NEWID	Patient ID	29874	156.8	89.3	1.0	313.0
F10_DAYS	f10qb Diary date	29874	142.2	190.2	-120.0	510.0

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
RATE_F10	Attack rate from Form 10	811	0.8	0.9	0.0	4.9
RATE_VAC	Attack rate from VERIFIED attack card	810	0.5	0.6	0.0	4.4
RATE_AAC	Attack rate from ANY attack card	810	0.8	0.9	0.0	4.9
ATT_F10	No. of attacks from Form 10	811	21.4	23.4	0.0	138.0
ATT_VAC	No. of attacks from VERIFIED attack card	810	13.1	16.8	0.0	122.0
ATT_AAC	No. of attacks from ANY attack card	810	21.0	23.2	0.0	138.0
DAY_F10	Days available from Form 10	811	27.1	3.2	7.0	28.0
DAY_VAC	Days available from VERIFIED attack card	811	26.8	3.6	0.0	28.0
DAY_AAC	Days available from ANY attack card	811	26.8	3.6	0.0	28.0
LOGR_F10	LN(attack rate) from Form 10	811	-0.9	1.4	-4.0	1.6
LOGR_VAC	LN(attack rate) from VERIFIED attack card	810	-1.6	1.5	-4.0	1.5
LOGR_AAC	LN(attack rate) from ANY attack card	810	-0.9	1.4	-4.0	1.6
NEWID	Patient ID	811	156.9	90.5	1.0	313.0

Data collection period

PERIOD	Frequency	Percent	Cumulative Frequency	Cumulative Percent
BL	8609	39.1	8609	39.1
M2	6376	29.0	14985	68.1
Y1	7025	31.9	22010	100.0

Pattern of Color

HAND_LTR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
A	5110	30.1	5110	30.1
B	1046	6.2	6156	36.3
C	3089	18.2	9245	54.5
D	744	4.4	9989	58.9
E	3205	18.9	13194	77.8
F	3774	22.2	16968	100.0

Frequency Missing = 12906

Data collection period

PERIOD	Frequency	Percent	Cumulative Frequency	Cumulative Percent
BL	12503	41.9	12503	41.9
M2	7867	26.3	20370	68.2
Y1	9504	31.8	29874	100.0

Data collection period

PERIOD	Frequency	Percent	Cumulative Frequency	Cumulative Percent
BL	313	38.6	313	38.6
M2	236	29.1	549	67.7
Y1	262	32.3	811	100.0